INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

IMPLEMENTATION OF THE NEW EU MEDICAL DEVICE REGULATIONS MDR (2017/745) AND IVDR (2017/746)

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Content

1 Introduction

The EU's Medical Device Regulation (EU 2017/745) and In Vitro Diagnostic Regulation (EU 2017/746) – MDR and IVDR, respectively – have entered into force on 26 May 2017. They shall be applied after the graduated transitional periods, ranging from six months to five years, have ended for different stakeholders.

Guidance documents are necessary to support the implementation of the forthcoming medtech Regulations, as these make provisions for implementing and delegated acts. Common specifications are required and the functioning of the medical device database, EUDAMED, is a prerequisite for the full employment of the new regulatory framework.

ISS Integrated Scientific Services has been entrusted by the Federal Office of Public Health FOPH (Bundesamt für Gesundheit BAG) to report on the ongoing developments related to these Regulations as well as their implementation and further elaboration. Subsequent reports will be published at three-month intervals. The thematic focus of the reports will be on the research, in particular clinical trials; related aspects of the Regulations and their implementation; and the relevant modules in EUDAMED.

2 Abbreviations

CCMO	Central Committee on Research Involving Human Subjects (Netherlands)
CECP	Clinical Evaluation Consultation Procedure
PECP	Performance Evaluation Consultation Procedure
EC	European Commission
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
EUTCA	EU-UK Trade and Cooperation Agreement
GSPR	General Safety and Performance Requirements
IMDD	Investigational Medical Device Dossier
IVDD	In Vitro Diagnostics Medical Devices Directive (98/79/EC)
IVDR	In Vitro Diagnostics Regulation (EU) 2017/746
JAZMP	Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
NoMA	Norwegian Medicines Agency
QMS	Quality Management System
UDI	Unique Device Identification

3 EU Commission issues notice to temporarily allow remote MDR and IVDR audits

The EU Commission published a notice on 11 January 2021 which proclaimed that notified bodies might temporarily perform QMS audits remotely in exceptional cases and on a case-by-case basis. As the inability of notified bodies to carry out on-site audits during the COVID-19 pandemic increases the risk of a shortage of vital devices, the European Commission responded to requests for exceptional temporary measures. The notice does not modify the legal texts of the Regulations but allows the Member States to exercise discretion

in allowing QMS audits under the MDR/IVDR to take place remotely. Notified bodies can, therefore, deviate from the MDR and IVDR requirement that QMS audits take place on-site if their competent authority allows this. Whether or not a notified body will be able to audit remotely, therefore, depends on the decision of its notifying member state.

Remote audits are possible in cases where this is justified and should:

- be time-limited, i.e. a notified body's decision on certification shall be limited to the time strictly necessary to allow a proper on-site audit to take place as soon as possible;
- be determined and justified on a case-by-case basis, and the circumstances in each case should be documented and adequately substantiated by the notified body; and
- not go beyond what is necessary to ensure the continued availability of safe and efficient products where the COVID-19 situation has specifically impeded the performance of on-site audits.

In addition, the Commission invites all Member States to systematically report on the application of temporary special measures. According to Team-NB, the competent authorities of the Member States are working together to provide guidance and achieve a Union-wide harmonised implementation of this measure.

3.1 MDCG issues additional guidance on remote audits

MDCG 2020-17 provides questions and answers related to the previous guidance MDCG 2020-4 on remote audits under the Directives the MDCG issued in April 2020. The new guidance does not address virtual audits in place of on-site audits in pandemics under the MDR. Still, it includes recommendations for notified bodies to prepare for remote audits, which may be relevant in the context of remote QMS assessments under the MDR/IVDR that the EC temporarily allows.

4 Expert panels

The EC has officially announced the clinical experts' names that have been appointed to the 12 expert panels. During the clinical evaluation consultation procedure (CECP) for devices (and the performance evaluation consultation procedure (PECP) for IVDs) these panels review notified body clinical evaluation work for certain high-risk medical devices. This review ensures additional scrutiny on the clinical evaluation of class IIb active devices that introduce or remove substances or implantable devices (non-well established) and class III products.

The EC added a tailored part within its medical device site on expert panels, providing rapid access to key expert panel information. In the future, opinions provided by the expert panels under the procedures and advice provided upon request to the European Commission, MDCG, EU countries, and notified bodies will be publicly available.

5 Implementing and delegated acts & guidelines

5.1 Updated implementation rolling plan and ongoing MDCG guidance document overview

Another update of the MDR and IVDR implementing measures rolling plan was issued in December 2020, along with a revised overview of the ongoing guidance documents the different MDCG subgroups are working on. The agenda listing the meetings of the subgroups in the weeks before the full application of the MDR was published in January 2021.

The following initiatives and implementing acts are intended to be accomplished/adopted in Q1 of 2021:

MDR:

- *Implementing act*
  Definition of detailed arrangements necessary for the setting up and maintenance of Eudamed. This is mainly related to support, change management and maintenance rules.
- *Standardisation request*
  MDR/IVDR Standardisation Request by the Commission to the relevant European standardisation organisations (CEN and CENELEC) for the development of harmonised European standards in the field of medical devices in support of the requirements of the new Regulations. The existing standards harmonised under the current Directives need to be revised to align them to the new legislative framework, and new standards need to be developed.

IVDR:

- *Implementing act*
  Rules to facilitate fulfilment of tasks by EU reference laboratories and to ensure their compliance with criteria.
- *Implementing act:*
  Fees for EURL services.

5.2 MDCG issues guidance on UDI assignment for spectacle lenses & ready readers

MDCG 2020-18 provides clarification on the UDI assignment obligations for manufacturers of reading glasses and spectacle lenses.

5.3 EMA provides information about dossier requirements for non-centrally authorised products and ancillary medicinal substances in a medical device

The EMA added specifications for dossier requirements for non-centrally authorised products and ancillary medicinal substances in a medical device on its website. The new document specifies the submission requirements of these devices in case applications are not submitted in the eCTD format.

5.4 EMA publishes webinar presentations on combination products regulated under MDR

The EMA has updated its website with additional presentations from its multi-stakeholder webinar to support the implementation of the regulatory requirements of the MDR on drug-device combinations. The webinar should support the necessary preparation for changes introduced by Article 117 of the MDR by providing the views and experience based on practical examples from Competent Authorities, notified bodies, the pharmaceutical industry, and medical device manufacturers.

6 EUDAMED

6.1 EUDAMED is live but industry remains concerned about national registration requirements as long as EUDAMED is voluntary

The first module of EUDAMED, the actor registration module, went live on 1 December 2020. Because actor registration is voluntary until 26 May 2022, individual Member States are within their rights to demand actor registration on a national basis under the MDR. The EC asked the Member States to promote the process and avoid double registration on a national level.

6.2 New document on management of legacy devices in EUDAMED issued

A newly issued guideline describes the registration requirements for legacy devices in EUDAMED, as they differ from MDR devices with regard to the registration deadline and UDI. For legacy devices, EUDAMED will require unique device identifiers, consisting of a EUDAMED DI (equivalent to the basic UDI) and a EUDAMED

ID (equivalent to the UDI-DI). EUDAMED will enable linking the linking the MDR product to the legacy device, once the MDD product becomes an MDR product and will automatically perform this linking if the legacy device and the MDR product have been assigned the same UDI-DI.

7 Notified body designation

7.1 19 notified bodies designated under the MDR, four under the IVDR

19 notified bodies are designated under the MDR and four under the IVDR. The MDR and IVDR designated notified body BSI UK has been removed from the NANDO database as the transition period of the Brexit withdrawal agreement between the EU and the UK has come to an end.

The following additional NBs with MDR designation are listed in NANDO:
- UDEM Adriatic, Croatia
- SGS Fimko, Finland
- Istituto Superiore di Sanità (ISS), Italy

8 Implementation activities on national levels

8.1 Netherlands: CCMO issues new investigational medical device dossier template

The CCMO issued a new version of the Investigational Medical Device Dossier (IMDD) template. The revised template is in line with the requirements of the MDR.

8.2 Norway: Updated information on language requirements for medical devices under the MDR

The Norwegian Medicines Agency (NoMA) added information to the country-specific language requirements that will apply under the MDR. The information shows that the requirement to provide labelling (including IFU) in Norwegian will continue to apply.

8.3 Slovenia: FAQ document on registration of Slovenian economic entities in Eudamed updated

The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (JAZMP) revised its FAQ document on actor registration to include the possibility to register in EUDAMED.

8.4 UK: New rules applicable for placing medical devices on the market as transition period ended

The UK and the EU reached an agreement on their future trade and cooperation arrangements. The EU-UK Trade and Cooperation Agreement (EUTCA) provides that there will be no tariffs and no quotas on bilateral trade in goods provided rules of origin and other technical requirements are met. The absence of agreement on conformity assessment means that new rules are applicable for medical devices in the UK.

8.5 Switzerland: Swissmedic issues form with standards for investigational medical devices in accordance with MDR

Swissmedic issued a new form to be used for clinical trials in accordance with Section 2.7 of Chapter II of Annex XV of the MDR. The form consists of two tables; the first one is used to indicate the applied standards, common specifications and scientific advice and how the compliance is demonstrated. The second table provides a matrix of the general safety and performance requirements (GSPR).

9 IVD-specific issues

9.1 Team-NB publishes consideration paper on IVDR date of application

Team-NB recently issued a consideration paper to address the conditions under which its members will support the current deadline of 26 May 2020 for full compliance with the IVDR. The requirements include that by the end of 2020, the infrastructure to perform IVD conformity assessments is available and half the 22 notified bodies designated under the IVDD are designated under the IVDR. If these conditions are not met, the Team-NB members will urge for a delay or a corrigendum to widen the eligibility of the grace period to include moderate/low-risk devices (classified as class B under the IVDR) and low-risk devices classified as class A sterile.

10 Miscellaneous

10.1 Team-NB publishes survey results on expiring certificates

Team-NB recently published survey results that predict an overload of notified bodies services in 2023/2024 due to certificates currently approved under the Directives that have to be re-certified under the MDR. To prevent high waves in the workload at the end of the grace period, Team-NB supports virtual/remote audits under the MDR and encourages manufacturers to submit their MDR applications as soon as possible (see Chapter 3).

10.2 Commission Implementing Decision (EU) 2020/1835 of 3 December 2020 harmonizes two standards

Commission Implementing Decision (EU) 2020/1835 of 3 December 2020 harmonised two standards that are relevant for conformity assessment carried out by notified bodies.

- IVD Directive
  EN ISO 15195:2019 Laboratory medicine – Requirements for the competence of calibration laboratories using reference measurement procedures (ISO 15195:2018)
- Regulation (EU) 2018/2067 on the verification of data and accreditation of verifiers
  EN ISO/IEC 17029:2019 Conformity Assessment – General principles and requirements for validation and verification bodies (ISO/IEC 17029:2019)

10.3 Team-NB publishes position paper on device related changes for drug-device combination products

Team-NB members adopted a position paper to interpret device-related changes in relation to a notified body opinion, as required under Article 117 of the MDR. The paper takes the position that changes to the medical device part should be assessed in accordance with the principles applicable to the assessment of substantial changes to medical devices to confirm that the device component remains compliant with Annex I of the MDR.

10.4 German industry associations call for a timely update of the MRA covering medical devices with Switzerland

In a joint initiative, several German associations call for the Mutual Recognition Agreement (MRA) between Switzerland and the EU to be updated promptly to prevent negative effects on patient care and the European medical device industry.

11 Sources

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